## Voluntary Nutrient Fortification

Fortification of foods with one or more micronutrients is used as a public health intervention intended to meet a defined population health problem. Perhaps the most widely cited example of successful fortification is the iodination of salt for the control and prevention of goiter and other iodine deficiency diseases (IDD). Salt iodination is now practiced in at least 107 countries, with an estimated overall coverage of 68 percent of households in those countries (ACC/SCN, 2000). Although IDD prevalence is falling rapidly, there are 130 countries in which IDD is still considered a public health problem. In Canada, fortification of free-running table salt is mandatory; in the United States, subject to state laws, it is voluntary. The iodination of salt continues to be actively promoted and has proven to be an extremely effective intervention in the iodine-deficient area of the Great Lakes basin of both countries. In the United States, the addition of niacin to cornmeal and flour for the control of pellagra, at one time endemic in the southeast, and the fluoridation of water to reduce dental caries have been clear success stories.

Efforts are now underway to achieve an equivalent success story for vitamin A and iron in developing countries. Technology for fortification is available but, because of the very limited use of processed foods, there is very limited opportunity for fortification in many of the countries most in need of fortified foods (IOM, 1998b).

In North America, a very large proportion of the food supply is processed, thus providing ample opportunity for fortification. The technology of fortification and preparation of nutrient premixes that are stable and do not cause taste, odor, or color changes are APPENDIX D 193

now available for a wide variety of products. The food industry thus can greatly increase the scope of fortification (more nutrients and more foods). However, with these advances in technology and greatly increased scope of opportunity comes the risk of overfortification.

In the past, when a clear public health problem was identified and only one or two foods were being fortified, the planning and monitoring of fortification was conceptually relatively easy. One could proceed along the lines exemplified for the mock fortification of fluid milk with vitamin A presented in Chapter 5. In the planning stage the potential benefit of nutrient addition, as well as the potential risk of excessive intake, could be predicted at a theoretical level. This could be done not only for the target groups where the public health problem was most severe, but also for other population segments likely to consume the fortified food. This is the type of preliminary planning that was done in the United States prior to increasing levels of fortification of bread flour with folate in the late 1990s. A defined public health problem existed, and only a few foods were targeted for the increased fortification.

Fortification planning has become complicated by three factors. First, as noted previously, the opportunity for fortification has increased tremendously and the number of foods involved has increased in the United States as manufacturers have implemented their own fortification decisions. Therefore, individuals may consume multiple sources of the fortificant. Second, the food industry is technologically ready to meet perceived needs for nutrients, and with nutrients for which the new recommended intakes may suggest increased need (IOM, 1997, 1998a, 2000b, 2001, 2002a), industry is anxious to respond. Third, there is an increased consumer awareness of nutrient composition of individual foods through nutrition labeling and a general rise in interest in nutrition and its potential health benefits. Over time, this has meant that labeled nutrient content and associated claims or inferred benefits have become important market influences. This places competitive pressure on the food industry to add more and larger amounts of nutrients to foods. Accordingly, the focus of nutrient fortification has shifted from carefully orchestrated and closely monitored interventions to address specified public health problems to a much less controlled and broader, nonorchestrated program of nutrient additions to meet market demands and competitive pressures. Where only a few fortified foods were marketed a few decades ago, there are now fortified and fabricated foods numbering in the thousands.

As an example, a recent study of U.S. food consumption (Berner et al., 2001) evaluated the impact of 246 different fortified foods on

nutrient intakes of populations. Children were found to be the most likely to consume fortified foods with 70 to 80 percent of children aged 1 to 10 years consuming foods fortified with vitamins A and C, thiamin, folate, or iron. In contrast, only 34 to 38 percent of adult women consumed these foods. A similar situation in Germany was reported (Sichert-Helert et al., 1999) where children aged 2 to 14 years consumed 479 different fortified food products.

In both the United States and Canada, food fortification has created difficult problems for government agencies involved in public health monitoring. Canada is currently formulating a new policy on fortification and designing new regulations under that policy (Health Canada, 1999). The fundamental difficulty is that fortification regulations (minimum and maximum levels to be added, compulsory versus voluntary addition, etc.) relate to single foods or classes of commodities that are used interchangeably. For example, stimulated by concerns over vitamin D deficiencies and possible links between excessive vitamin D intake and cases of idiopathic hypercalcemia, Canadian regulations were modified to allow the addition of vitamin D to all types of milks, but to prohibit its addition to most other types of foods. The milk products were considered to be interchangeable and mutually exclusive.

The regulatory framework was developed to address the control of rickets in Canada, while at the same time avoiding the problem of infantile hypercalcemia, which had been attributed to excessive intakes of vitamin D (perhaps combined with high calcium intakes). This approach appeared to be effective in addressing the public health problem, but did not guarantee that every individual would ingest the recommended amount of vitamin D.

Many have urged that the regulations be eased to allow addition of vitamin D to a much wider range of foods, as is allowed in the United States. Such a relaxation of control would increase the likelihood that those who drank very little or no milk could get adequate vitamin D from another food. However, there is also the concern that excessive intakes may result if individuals consume several fortified foods. Thus, a dilemma exists for regulatory agencies.

As stated earlier, with compulsory fortification of only a few foods, mock fortification studies (such as the vitamin A example in Chapter 5) can be conducted to assess expected benefits and potential risks associated with different levels of fortification. However, because the number of fortified foods has increased, it is no longer possible to run meaningful mock fortification scenarios.

Furthermore, it has not been possible for food composition databases to stay current with the increasing numbers of foods fortified APPENDIX D 195

with an array of different nutrients added at different levels. Intake data collected in national surveys would have to carry brand names and perhaps manufacturing dates in order to have accurate assessments of intake for use in planning fortification programs. It is not currently possible to use large national dietary studies to monitor the public health impacts of fortification.

An additional concern was highlighted by Whittaker and colleagues (2001) who examined iron and folate levels in 29 fortified breakfast cereals. The analyzed content of iron in these cereals ranged from 80 to 190 percent of label values, with 21 of the 29 cereals containing 120 percent or more above label values. Analyzed values for folate ranged from 98 to 320 percent of label values. In addition, label values were based on a serving size of 30 g, but the median measured serving size was 47 g for women and 61 g for men. Consequently, intakes of iron and folate would be considerably higher than what would be estimated based on standard portion sizes and nutrition label information, with the prevalence of intakes greater than the Tolerable Upper Intake Level being much higher than predicted.

Food fortification thus has become a risk-risk situation that requires balancing concerns of inadequate intakes with concerns of excessive intakes. One approach to solve this problem is to tightly regulate additional fortification efforts, but then the individuals who do not consume the existing fortified products would not have other sources available to achieve adequate dietary intake. Another option is to allow industry to respond to market demand and increase fortification, but then the risk of excessive levels of intake among those consuming multiple fortified products or high amounts of single fortified foods increases.

Nutritionists generally do not think in terms of adequacy of individual foods. Rather, limits of intake (inadequacy to excess) are based on "habitual dietary intakes," or the self-selected mix of foods consumed over long periods by individuals. Fortification regulations have to relate to single foods or groups of foods. The increasing use of over-the-counter pharmaceutical supplements and dietary supplements, potentially by the same health-conscious people who scan nutrition labels for foods with the highest available nutrient levels, must also be factored into decisions on nutrient fortification policy.